Femoral vein homograft for neoaortic reconstruction in the Norwood stage 1 operation: A follow-up study

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Objective: The aim of this study was to analyze our experience with the cryopreserved femoral vein homograft in comparison with standard biomaterials for neoaortic reconstruction in the Norwood stage 1 operation.

Methods: All patients who underwent the Norwood operation from September 2004 to April 2011 were analyzed retrospectively (n = 107). Patients were grouped into group A (cryopreserved femoral vein homograft; n = 72) or group B (other; n = 35). Intergroup comparisons and dimensional analyses of all available angiograms were performed. Two surgical techniques, “standard homograft cuff” and “homograft tube,” were compared.

Results: Multivariable Cox regression analysis revealed use of biomaterial other than femoral vein ($P = .01$; hazard ratio, 3.0; 95% confidence interval [CI], 1.4-6.4), weight less than 2.5 kg at the time of stage 1 ($P = .01$; hazard ratio, 3.7; 95% CI, 1.7-7.8), and need for extracorporeal membrane oxygenator support after stage 1 ($P < .001$; hazard ratio, 13.8; 95% CI, 5.9-31.9) as significant independent predictors of overall mortality. Improved late survival at 48 months was seen with the femoral vein homograft compared with other biomaterials when a “homograft tube with end-to-side ascending aortic reimplantation technique” was used (group A [75%] vs group B [44%]; $P = .03$). With the use of the “homograft cuff technique,” survival was similar for femoral vein homografts and other biomaterials (group A [67%] vs group B [61%]; $P = .85$). Similar neoaortic coarctation rates were seen in both groups (A: 25/59 [42%] vs B: 12/26 [46%]; $P = .81$). A progressive increase in the diameter of the neoaorta was seen over time in both groups with both technical modifications (tube grafts pre-stage 2 vs pre-stage 3: group A [10.61 mm $\pm$ 1.93 vs 13.74 mm $\pm$ 3.16] [$P < .001$] and group B [13.93 mm $\pm$ 6.71 vs 17.38 mm $\pm$ 5.92] [$P = .049$]; cuff repair pre-stage 2 to pre-stage 3: group A [13.98 mm $\pm$ 2.13 vs 19.09 mm $\pm$ 4.18] [$P = .002$] and group B [16.06 mm $\pm$ 3.05 vs 19.73 mm $\pm$ 2.93] [$P < .001$]). The neoaortic Z-scores were generous with the use of homograft cuffs and modest when homograft tubes were used and maintained in range over the follow-up time.

Conclusions: Survivals are improved with the use of femoral vein homograft for neoaortic reconstruction for Norwood stage 1 operation, especially when used as a homograft tube with end-to-side aortic reimplantation. Femoral vein homografts have similar recoarctation rates compared with standard biomaterials. Progressive growth/dilation of the neoaorta in proportion to somatic growth is seen with femoral vein tube grafts. (J Thorac Cardiovasc Surg 2013;146:550-6)

Aortic or pulmonary homografts are the most commonly used supplemental biomaterials for neoaortic reconstruction in the stage 1 Norwood operation. The variable wall thickness of aortic homografts and the length limitation of the pulmonary homografts pose technical challenges for neoaortic reconstruction, especially in patients with a diminutive ascending aorta. Additionally, limited availability of pediatric aortic and pulmonary homografts and their high cost have led to development of alternative methods of

neoaortic reconstruction for the Norwood stage 1 procedure.¹⁻³ We⁴ reported the use of cryopreserved femoral vein homograft as an alternative biomaterial for neoaortic reconstruction in the stage 1 Norwood operation in 2009.⁴ This report documents short- to intermediate-term follow-up.

METHODS

Owing to the retrospective nature of the study, the institutional review board at Children's National Medical Center approved waiver of documented consent. All patients who underwent the Norwood stage 1 operation for hypoplastic left heart syndrome (HLHS) or HLHS variants between September 2004 and April 2011 were included in the study. The patients were grouped according to the homograft material used for neoaortic reconstruction into group A (femoral vein homograft) and group B (material other than femoral vein homograft, ie, aortic or pulmonary homograft, autologous pericardium, and prosthetic material). Each group was further divided into 2 categories by type of repair: standard homograft cuff technique or circumferential tube homograft (with end-to-side ascending aortic anastomosis, or without end to side aortic reimplantation or the “double-barrel” technique). Demographic, preoperative, intraoperative, postoperative, and follow-up data were reviewed.

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Disclosures: Authors have nothing to disclose with regard to commercial support. Received for publication June 15, 2012; revisions received Oct 12, 2012; accepted for publication Dec 5, 2012; available ahead of print Jan 14, 2013.

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0022-5223/\$36.00

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<http://dx.doi.org/10.1016/j.jtcvs.2012.12.010>

Abbreviations and Acronyms

CI	= confidence interval
ECMO	= extracorporeal membrane oxygenator
HLHS	= hypoplastic left heart syndrome

Operative Technique

All patients underwent stage 1 Norwood reconstruction via a median sternotomy, hypothermic low-flow cardiopulmonary bypass, and circulatory arrest. A pH-stat strategy, goal hematocrit on bypass of more than 30%, and deep hypothermic circulatory arrest for arch reconstruction were applied in all patients. The technical aspects of the surgical procedure are widely described elsewhere.⁵ It is our preference to use a right ventricle–pulmonary artery conduit as a source for pulmonary blood flow unless it is technically not feasible (left ventricular morphology of the single ventricle, inaccessible right ventricular infundibulum owing to cardiac position, or presence of large coronaries contraindicating a ventriculotomy), and then a systemic–pulmonary artery shunt is used. Neo-aortic reconstruction was performed using either a homograft cuff or a circumferential homograft tube. Depending on the size of the ascending aorta, either end-to-side ascending aortic reimplantation was performed or a homograft tube was used without end-to-side ascending aortic reimplantation.

Homograft Cuff Technique

After division of the ductus arteriosus at its junction with the descending aorta, the resulting aortotomy is extended distally onto the descending aorta for several millimeters and proximally along the undersurface of the aortic arch, ascending to the level of the divided main pulmonary artery. An anastomosis is fashioned between the proximal portion of the divided main

pulmonary artery and the filleted aorta with a supplementary cuff of homograft (Figure 1, A).

Circumferential Tube Homograft Technique

With end-to-side ascending aortic reimplantation. The ductus arteriosus is transected at its junction with the descending aorta. The ascending aorta is divided at its junction with the proximal arch. The resulting orifice in the proximal arch is extended across the undersurface of the aortic arch through the ductal orifice and beyond onto the descending aorta beyond the coarctation shelf. The homograft, beveled appropriately, is used as a circumferential tube to connect the divided proximal pulmonary artery to the undersurface of the arch and proximal ascending aorta. With the neo-aorta filled with saline, to both deair and distend the homograft, an appropriate-sized opening is created along the right lateral aspect of the proximal homograft. The ascending aorta is spatulated and anastomosed end to side to the homograft tube with interrupted sutures at the heel and the remainder continuous 7-0 Prolene polypropylene (Ethicon, Inc, Somerville, NJ) (Figure 1, B). Creation of a long ascending aortic anastomosis limits the nongrowing rim to a few millimeters at the proximal and distal homograft tube anastomotic sites only, with the majority of the homograft circumference still having the growth potential.

Without end-to-side aortic reimplantation, “double-barrel.” The “double-barrel” technique is suitable for patients with an ascending aorta larger than 5 mm. Often the arterial cannula is placed directly into the mid to distal ascending aorta along its right lateral aspect. After division of the ductus arteriosus, the resulting aortotomy is extended distally onto the descending aorta. Proximally, the aortotomy is extended along the undersurface of the aortic arch to the ascending aorta. It is important to extend the ascending aortotomy inferiorly beyond the aortic cannulation site to avoid narrowing of the ascending aorta at this level. The circumferential homograft tube is shaped appropriately and a beveled

FIGURE 1. Technical modifications used for neo-aortic reconstruction. A, Homograft cuff technique. B, Homograft tube with end-to-side ascending aortic reimplantation. C, Homograft tube without end-to-side aortic reimplantation, “double-barrel.” Black arrow depicts site of aortic cannulation. Lateral aortograms for the 3 techniques. D, Homograft cuff. E, Homograft tube with end-to-side ascending aortic reimplantation. F, Homograft tube without end-to-side aortic reimplantation, “double-barrel.” White line depicts sites of angiographic measurements for each of the techniques.

anastomosis is fashioned to the aortotomy. The homograft tube is cut to length and anastomosed end to end to the proximal divided main pulmonary artery (Figure 1, C).

Angiographic Data

Neo-aortic dimensions were estimated from all available angiograms from all cardiac catheterizations performed (pre-stage 2, pre-stage 3, and others). The lateral projection of the aortic arch angiogram was used to measure the diameter of the ascending neo-aorta in millimeters (Figure 1, A to C). To minimize interobserver variability, 2 independent observers made measurements and the average of the 2 was used for analysis. Dimensional comparisons were made between group A and group B, as well as between “homograft cuffs” and “homograft tubes.” Ascending aortic Z-scores were calculated using standard published data.⁶

Neo-aortic coarctation was defined by the need for intervention owing to narrowing of the reconstructed aorta (balloon angioplasty or surgical aortic arch augmentation) at any time during the study period. The criteria for reintervention at the time of cardiac catheterization were significant angiographic narrowing (coarctation index <0.7) or pressure gradient of more than 15 mm Hg (mean)⁸ or more than 20 mm Hg (peak). Surgical arch augmentation was considered for failed balloon angioplasty or aortic arch narrowing considered unsuitable for balloon angioplasty.

Statistical Analysis

All continuous data are presented as mean $\pm$ standard deviation, and categorical data are presented as number (percentages). Patient survival was analyzed with the Kaplan-Meier method and groups were compared using the log-rank test. Cox multivariable regression analysis was used to determine independent risk factors of mortality with hazard ratios to allow for censoring and to adjust for covariates, including biomaterial, patient weight, and need for support with an extracorporeal membrane oxygenator (ECMO). Inasmuch as femoral vein homograft recipients (group A) were the more contemporary patients being compared with historical controls (group B), date of operation was included in the multivariable analysis, to account for the “era effect.”

Ascending aorta diameter and Z-scores followed a normal Gaussian-shaped distribution and therefore were compared between femoral vein homograft and other biomaterial groups using the Student *t* test. Comparison of aortic diameter for each group between pre-stage 2 and pre-stage 3 were assessed using paired *t* tests. Rate of neo-aortic coarctation was compared using Fisher's exact test and logistic regression was applied to identify predictors of coarctation. The number of operative survivors constituted the denominator for dimensional and neo-aortic coarctation analyses. Statistical analysis was performed using SAS version 9.2 (SAS Institute, Inc, Cary, NC).

RESULTS

Between September 2004 and April 2011, a total of 107 patients underwent the Norwood stage 1 procedure. Cryopreserved femoral vein homograft was used in 72 patients (group A), and in 35 patients biomaterials other than femoral vein were used for neo-aortic reconstruction (group B) (31 aortic-pulmonary homograft, 3 autologous pericardium, 1 polytetrafluoroethylene [Gore-Tex; registered trademark of W. L. Gore & Associates, Inc, Flagstaff, Ariz]). In February 2007, we switched to exclusively using cryopreserved femoral vein homograft for neo-aortic reconstruction in the Norwood stage 1 operation. All patients who underwent the procedure between February 2007 and April 2011 received the femoral vein homograft (group A), whereas before this period (September 2004 and February

2007) all patients underwent the procedure using other biomaterials (group B).

The standard homograft cuff technique was used in 15 patients in group A and 18 patients in group B. A total of 48 patients (32 group A, 16 group B) underwent neo-aortic reconstruction using a circumferential homograft tube with end-to-side ascending aortic reimplantation. The majority of patients (84%) in group A that underwent this technique had a diminutive ascending aorta (<2 mm). This was also true in group B (81%). The presence of an adequate-sized ascending aorta allowed neo-aortic reconstruction using a circumferential homograft tube without end-to-side aortic reimplantation in 26 patients in group A, whereas this was the technique used for only 1 of the patients in group B.

The anatomic, preoperative, intraoperative, and postoperative details of all patients are detailed in Tables 1 and 2. To date, 78 patients have undergone stage 2 (bidirectional Glenn) and 45 stage 3 (Fontan) procedures.

Mortality

There were a total of 22 (20.5%) operative deaths (13 in group A; 9 in group B), with nonsignificant differences between the 2 groups (group A, 18.1%; group B, 25.7%; $P = .45$). Excluding the 4 nonhomograft patients from group B (3, autologous pericardium; 1, polytetrafluoroethylene) did not affect the mortality (group A, 18.1%; group B, 25.8%; $P = .43$). At a median follow-up of 3.4 years (1.6-5.2 years), there were 7 late deaths in group A and 7 in group B, amounting to an overall mortality of 27.8% in group A and 45.7% in group B ($P = .08$). There were a total of 4 interstage 1-2 deaths (1, group A; 3, group B) and 6 interstage 2-3 deaths (5, group A; 1, group B). Death after Fontan completion occurred in 4 patients (1, group A; 3, group B) (Table 1).

Multivariable Cox regression analysis revealed the use of biomaterial other than femoral vein ($P = .01$; hazard ratio, 3.0; 95% confidence interval [CI], 1.4-6.4), weight less than 2.5 kg at the time of stage 1 ($P = .01$; hazard ratio, 3.7; 95% CI, 1.7-7.8), and need for ECMO support after stage 1 ($P < .001$, hazard ratio, 13.8; 95% CI, 5.9-31.9) as significant independent predictors of overall mortality (Table 3). Improved late survival at 48 months was seen with the femoral vein homograft compared with other biomaterials when a “homograft tube with end-to-side ascending aortic implantation technique” was used (group A [75%] vs group B [44%]; $P = .03$). With use of “homograft cuff technique,” survival was similar for femoral vein homografts and other biomaterials (group A [67%] vs group B [61%]; $P = .85$) (Figure 2).

Dimensional Analysis

By the end of the study period, a total of 202 cardiac catheterizations had been performed in 71 survivors. These included 147 planned (92, pre-stage 2 and 55, pre-stage 3)

TABLE 1. Comparison of anatomic, preoperative, intraoperative, postoperative, and neo-aortic dimensions

Variable	Overall (n = 107)	Group A (n = 72)	Group B (n = 35)	P value
Anatomic				
Sex				
Male	54 (50%)	34 (47%)	20 (57%)	—
Female	53 (50%)	38 (53%)	15 (43%)	—
Prematurity (<36 wk gestation)	13 (12%)	9 (13%)	4 (11%)	—
Weight < 2.5 kg	17 (16%)	11 (15%)	6 (17%)	—
HLHS	71 (66%)	47 (66%)	24 (69%)	—
Aortic atresia/mitral atresia	49 (69%)	32 (68%)	17 (71%)	—
Aortic stenosis/mitral stenosis	13 (18%)	10 (21%)	3 (13%)	—
Aortic atresia/mitral stenosis	9 (13%)	5 (11%)	4 (16%)	—
HLHS variants				
DORV	15 (14%)	9 (13%)	6 (17%)	—
Unbalanced AVC defect	10 (9%)	8 (11%)	2 (6%)	—
Tricuspid atresia	5 (5%)	2 (3%)	3 (9%)	—
DILV	5 (5%)	4 (6%)	1 (2%)	—
D-TGA	1 (1%)	1 (1%)	0 (0%)	—
Single ventricle morphology				
Right	99 (92%)	65 (90%)	34 (97%)	—
Left	6 (6%)	5 (7%)	1 (3%)	—
Ambiguous	2 (2%)	2 (3%)	0 (0%)	—
Intact/restrictive interatrial septum	10 (9%)	7 (10%)	3 (9%)	—
Diminutive ascending aorta (<2 mm)	42 (39%)	28 (39%)	14 (40%)	—
Size (mm) of ascending aorta (mean)	3.7 ± 2.1	3.5 ± 1.9	4.0 ± 2.3	.36
Intraoperative				
Technique				
Homograft cuff	33 (30%)	15 (20%)	18 (51%)	—
Circumferential tube homograft with end-to-side ascending aortic anastomosis	48 (45%)	32 (44%)	16 (46%)	—
Circumferential tube homograft without end-to-side aortic anastomosis	27 (25%)	26 (36%)	1 (3%)	—
RV-PA conduit	94 (88%)	63 (87%)	31 (89%)	—
Systemic-PA shunt	13 (12%)	9 (13%)	4 (11%)	—
Postoperative				
Postoperative ECMO	23 (21%)	16 (22%)	7 (20%)	—
Operative mortality	22 (20.5%)	13 (18.1%)	9 (25.7%)	.45
Late mortality	13 (12.1%)	7 (9.7%)	7 (20.0%)	—
Overall mortality	36 (33.6%)	20 (27.8%)	16 (45.7%)	.08
Interstage death (1 → 2)	25 (23.3%)	1 (1.4%)	3 (8.6%)	—
Interstage death (2 → 3)	7 (6.5%)	5 (6.9%)	1 (2.9%)	—
Follow-up, y (median)	3.0 (1.8-5.0)	2.2 (1.6-3.0)	5.4 (4.9-6.3)	<.001
Neo-aortic coarctation				
Neo-aortic coarctation*	37 (37/85 = 44%)	25 (25/59 = 42%)	12 (12/26 = 46%)	.81
Coarctation with circumferential tube homograft	24 (24/57 = 42%)	19 (19/46 = 41%)	5 (5/11 = 45%)	1.00
Coarctation with homograft cuff	13 (13/28 = 46%)	6 (6/13 = 46%)	7 (7/15 = 47%)	1.00
Narrowing distal to LSA	33 (33/37 = 89%)	22 (22/25 = 88%)	11 (11/12 = 92%)	1.00
Narrowing in ascending aorta	7 (7/37 = 19%)	5 (5/25 = 20%)	2 (2/12 = 16%)	1.00
Narrowing distal to LSA and in ascending aorta (at separate times)	3 (3/37 = 8%)	2 (2/25 = 8%)	1 (1/12 = 8%)	1.00

Continuous data are presented as mean ± standard deviation, and categorical data presented as number (percentages). HLHS, Hypoplastic left heart syndrome; DORV, double-outlet right ventricle; AVC, atrioventricular canal; DILV, double-inlet left ventricle; D-TGA, dextrotransposition of the great arteries; RV, right ventricle; PA, pulmonary artery; ECMO, extracorporeal membrane oxygenation; LSA, left subclavian artery. *Denominator = number of survivors.

and 45 unplanned cardiac catheterizations. Results of the dimensional analysis are detailed in Table 4.

Group A versus group B. The size of the neo-aorta was similar in both groups if “tube grafts” were used. Use of cuff grafts resulted in larger neo-aortic Z-scores in group B

at pre-stage 2 cardiac catheterization (group A, 2.62 ± 1.87 vs group B, 4.32 ± 2.07 ; $P = .043$). At pre-stage 3 cardiac catheterization, the difference still existed although was not significant (group A, 2.77 ± 2.83 vs group B, 4.57 ± 1.33 ; $P = .106$ [Table 4]).

TABLE 2. Comparison of neo-aortic coarctation by type of repair

	Homograft tube	Homograft cuff	P value
Overall	24 (42%)	13 (46%)	.82
Group A	19 (41%)	6 (46%)	.76
Group B	5 (45%)	7 (47%)	1.00

Interval change. With time, a progressive increase in the diameter of the ascending aorta as measured by absolute neo-aortic diameter (Figure 3, A and B) was seen in both groups with both technical modifications (tube grafts pre-stage 2 vs pre-stage 3: group A [$10.61 \text{ mm} \pm 1.93$ vs $13.74 \text{ mm} \pm 3.16$; $P < .001$] and group B [$13.93 \text{ mm} \pm 6.71$ vs $17.38 \text{ mm} \pm 5.92$; $P = .049$] [Figure 3, A]; cuff repair pre-stage 2 to pre-stage 3: group A [$13.98 \text{ mm} \pm 2.13$ vs $19.09 \text{ mm} \pm 4.18$; $P = .002$] and group B [$16.06 \text{ mm} \pm 3.05$ vs $19.73 \text{ mm} \pm 2.93$; $P < .001$] [Figure 3, B]).

There was no change in the neo-aortic Z-scores with time in either group with either technical modification (tube grafts pre-stage 2 vs pre-stage 3: group A (-0.38 ± 1.89 vs 0.00 ± 2.08 ; $P = .42$) and group B (1.76 ± 4.60 vs 2.27 ± 4.13 ; $P = .88$) (Figure 3, C); cuff repair pre-stage 2 to pre-stage 3: group A (2.62 ± 1.87 vs 2.77 ± 2.83 ; $P = .38$) and group B (4.32 ± 2.07 vs 4.57 ± 1.33 ; $P = .16$) (Figure 3, D). The neo-aortic Z-scores were generous with the use of homograft cuffs. When homograft tubes were used the neo-aorta was closer to normal size.

Cuffs versus tubes. Abnormal dilation of the neo-aorta (Z-score >2) was seen in both groups with the “cuff modification.” Significantly higher neo-aortic diameters and Z-scores were seen for the “cuff technique” compared with the “tube grafts” at both pre-stage 2 and pre-stage 3 for group A patients (pre-stage 2 diameter group A: cuff 13.98 ± 2.13 vs tube 10.61 ± 1.93 ; $P < .001$; pre-stage 2 Z scores group A: cuff 2.62 ± 1.87 vs tube -0.38 ± 1.89 ; $P < .001$; pre-stage 3 diameter: cuff 19.09 ± 4.18 ; tube 13.74 ± 3.16 ;

TABLE 3. Predictors of mortality by multivariable Cox proportional hazards regression

Variable	P value	Hazard ratio	95% CI
Age at stage 1, d	.53	—	—
Weight at stage 1 (<2.5 kg)	.01*	3.7	1.7-7.8
Diagnosis (HLHS vs variant)	.15	—	—
Morphology (LV vs RV)	.68	—	—
Shunt (BT vs Sano)	.08	—	—
Repair type (cuff, tube, DB)	.70	—	—
ECMO after stage 1	<.001*	13.8	5.9-31.9
Ascending aorta diameter <2 mm	.25	—	—
Era of operation (2004-2011)	.86	—	—
Biomaterial (others vs FV)	.01*	3.0	1.4-6.4

CI, Confidence interval; HLHS, hypoplastic left heart syndrome; LV, left ventricle; RV, right ventricle; BT, Blalock-Taussig; DB, double-barrel; ECMO, extracorporeal membrane oxygenation; FV, femoral vein. *Statistically significant predictor.

FIGURE 2. Kaplan-Meier curve representing survival after Norwood stage 1 operation. *Significant difference with use of circumferential femoral vein homograft with end-to-side anastomosis of the ascending aorta.

$P < .001$; pre-stage 3 Z score: cuff 2.77 ± 2.83 ; tube 0.00 ± 2.08 ; $P = .008$). A similar trend was noted in group B but was not significant.

Neo-aortic coarctation. Of the 85 survivors, 37 (44%) had neo-aortic coarctation as defined by need for balloon angioplasty and/or surgical arch augmentation. Similar neo-aortic coarctation rates were seen in both groups (A: 25/59 [42%]; B: 12/26 [46%]; $P = .81$) (Table 1). There was no difference in coarctation rate by type of repair (tube: 24/57 [42%]; cuff: 13/28 [46%]; $P = .82$) (Table 2). The narrowing was distal to the left subclavian artery in 89% (33/37; group A, 22; group B, 11) of patients with re-coarctation. Ascending neo-aortic narrowing was seen in 7 patients (group A, 5; group B, 2), all of whom had a circumferential tube homograft repair. Three patients had narrowing of the neo-aorta at both locations, albeit at separate points in time.

Balloon angioplasty alone was required in 19 patients in group A and 7 in group B. Poor response to balloon angioplasty led to surgical arch augmentation in 2 patients in group A and 1 patient in group B. Location and nature of the narrowing prompted direct operative aortic intervention in 3 patients in group A and 4 in group B. Of the 5 patients in group A with ascending neo-aortic narrowing, 3 had surgical aortic augmentation, 1 had balloon angioplasty, and 1 required surgical aortic augmentation after angioplasty; both the patients in group B with ascending neo-aortic narrowing underwent surgical aortic augmentation. Of all patients with ascending neo-aortic narrowing, 2 patients in group A and 1 in group B also had additional neo-aortic coarctation distal to the left subclavian artery successfully treated with balloon angioplasty at the pre-stage 2 cardiac catheterization. Multivariable analysis confirmed that diagnosis of HLHS was the only significant predictor of coarctation of the neo-aorta ($P = .008$).

TABLE 4. Predictors of mortality by ascending aorta size and Z scores for patients who underwent the Norwood procedure with femoral vein and other homografts stratified by repair type

Pre-Glenn cath	Femoral vein (group A)		Other homografts (group B)		P value
	Mean ± SD	n	Mean ± SD	n	
Tube or double-barrel					
Neo-aorta, mm	10.61 ± 1.93†	39	13.93 ± 6.71	7	.240
Z-score	−0.38 ± 1.89†	39	1.76 ± 4.60	7	.268
Cuff repair					
Neo-aorta, mm	13.98 ± 2.13	11	16.06 ± 3.05	14	.067
Z-score	2.62 ± 1.87	11	4.32 ± 2.07	14	.043*

Pre-Fontan cath	Mean ± SD		Mean ± SD		P value
		n		n	
Tube or double-barrel					
Neo-aorta, mm	13.74 ± 3.16†	19	17.38 ± 5.92	6	.200
Z-score	0.00 ± 2.08†	18	2.27 ± 4.13	6	.246
Cuff repair					
Neo-aorta, mm	19.09 ± 4.18	9	19.73 ± 2.93	12	.683
Z-score	2.77 ± 2.83	9	4.57 ± 1.33	12	.106

SD, Standard deviation. *Statistically significant, Student *t* test. †Statistically significant difference between tube or double-barrel versus cuff repair in the femoral vein group (*P* < .01). No significant differences between tube or double-barrel versus cuff repair among other homografts.

FIGURE 3. Neo-aortic size with follow-up. Absolute neo-aortic diameter in millimeters by type of repair. A, Circumferential tube homograft with or without end-to-side ascending aortic anastomosis: Femoral vein homografts (group A) vs others (group B). B, Homograft cuff: Femoral vein homografts (group A) vs others (group B). Neo-aortic Z scores. C, Circumferential tube homograft with or without end-to-side ascending aortic anastomosis: Femoral vein homografts (group A) vs others (group B). D, Homograft cuff: Femoral vein homografts (group A) vs others (group B). BDG, Bidirectional Glenn.

DISCUSSION

The use of femoral vein homograft offers several advantages for neoaortic reconstruction in the Norwood stage 1 operation. Inasmuch as cryopreserved femoral vein homografts are harvested from adult donors, they are widely available compared with pediatric aortic or pulmonary homografts. In addition to its lower cost, femoral vein homograft is supplied as 20- to 30-cm long segments tapering from 15 to 16 to 10 to 11 mm in diameter, allowing intraoperative selection of optimum-sized segment. The femoral vein tissue is thin walled, thus being particularly suitable for end-to-side reimplantation of a particularly diminutive ascending aorta, thus greatly simplifying this technically challenging operation. Despite its thinness, the tissue is strong and hemostatic.⁴ The femoral vein also offers the versatility of being used as a “homograft cuff” in a standard stage 1 Norwood operation when the ascending aorta is not diminutive, or for use as a “tube graft without end-to-side anastomosis of the ascending aorta (double-barrel technique)” for HLHS variants with a nearly normal sized ascending aorta.

In this study the use of femoral vein homograft was a negative predictor of mortality, with significant survival benefit in the higher risk patients with diminutive ascending aorta (<2 mm) when used as a tube graft with end-to-side ascending aortic reimplantation. Our findings of weight less than 2.5 kg at stage 1 and need for ECMO in the immediate postoperative period being predictive of mortality are consistent with previous reports.^{9,10} The characteristics of the groups were similar with regard to prematurity, weight less than 2.5 kg, presence of intact/restrictive atrial septum, prevalence of a diminutive ascending aorta, and need for postoperative ECMO. No correlation between date of stage 1 operation (era effect) and mortality was found across the entire study period.

There was no difference in the rate of neoaortic coarctation evident between biomaterials used or between types of repair. In an attempt to focus on late aortic arch obstruction, we excluded operative mortalities from the neoaortic coarctation analysis. Additionally, strict definition of recoarctation and low threshold for intervention may overestimate the overall neocoarctation rates in this study. Nonetheless, the similar rates of neoaortic recoarctation between groups suggest that femoral vein homograft imparts no greater risk of recoarctation than standard biomaterials.

Although there are growing concerns with severely dilated neo-aortas after the stage 1 Norwood operation with the standard cuff technique, the use of tube grafts has a risk of subsequent neoaortic stenosis owing to their lack of growth potential. It is reassuring in this study that the use of homograft tubes did not lead to higher rates of neoaortic stenosis than did the cuff grafts. On the other hand, an interesting progressive increase in the neoaortic size was seen commensurate with somatic growth. In fact, the

neo-aortic Z-scores were maintained in the modestly dilated range. This could be due to dilation of the homograft with time, especially with femoral vein homografts, supplemented by the growth potential of the incorporated ascending aorta. Technical modifications such as making the end-to-side aortic reimplantation as long as possible limits the rim of nongrowing circumference to a few millimeters at the proximal and distal homograft tube anastomotic sites only, with the majority of the homograft circumference still left with growth potential.

This report has the limitation of being a single-center, retrospective study with a limited number of patients and short- to intermediate-term follow-up. Greater longitudinal follow-up is needed to determine the long-term outcomes of these patients. However, this is the only report of an attractive alternative biomaterial and technique for neoaortic reconstruction for the stage 1 Norwood operation.

CONCLUSIONS

Survivals are improved with the use of the femoral vein homograft for neoaortic reconstruction for the Norwood stage 1 operation, especially when used as a homograft tube with end-to-side aortic reimplantation. Femoral vein homografts have recoarctation rates similar to those of standard biomaterials. With appropriate technical modifications, homograft tube grafts and homograft cuffs have similar recoarctation rates. Progressive growth/dilation of the neo-aorta in proportion to somatic growth is seen with femoral vein tube grafts. The cryopreserved femoral vein homograft is an excellent alternative biomaterial for neoaortic reconstruction in the Norwood stage 1 operation.

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